

Package leaflet: Information for the patient

N-CORT 0.055% Nasal Spray, suspension

For use as a nasal spray.

- **Active substance(s):** (w/w%)
Triamcinolone acetonide 0.055
Each application contains 55 micrograms of triamcinolone acetonide.
- **Excipient(s):** Disodium edetate, dextrose monohydrate, microcrystalline cellulose and carboxymethyl cellulose sodium, polysorbate 80, benzalkonium chloride 50%, dilute hydrochloric acid, dilute sodium hydroxide and purified water

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher or lower** dose other than the recommended to you.*

What is in this leaflet?

1. ***What N-CORT is and what it is used for***
2. ***What you need to know before you use N-CORT***
3. ***How to use N-CORT***
4. ***Possible side effects***
5. ***How to store N-CORT***

1. What N-CORT is and what is it used for

- N-CORT contains triamcinolone acetonide as active substance. It is presented in a packaging containing 16.5 g suspension for 120 actuations with a metered dose valve and a nasal applicator. Each spray dose contains 55 micrograms of triamcinolone acetonide.
- N-CORT is a homogeneous (uniform) looking opaque (non-transparent) suspension (solid-liquid mixture).
- N-CORT is an antiallergic corticosteroid. It is used to treat symptoms of seasonal and perennial allergic rhinitis.

2. What you need to know before you use N-CORT

DO NOT use N-CORT:

If:

- You or your children above 6 years of age are allergic to triamcinolone acetonide or to any of the other ingredients.

Warnings and precautions

- If you or your child are/is taking steroid therapy that affects the whole body (systemic) or if you or your child have/has previously received steroid therapy that affects the whole body (systemic), there may be a possibility that the adrenal gland function may be impaired when switching to N-CORT. (Your doctor may want to follow up you or your children closely in order to prevent acute adrenal gland failure)

Use of a higher dose than recommended may result in suppression of the adrenal system.

- If you or your child have/has fungal infection in nose or larynx (In such cases your doctor will stop N-CORT treatment temporarily and will give you required local therapy.)
- If you or your child have/has experienced recent wound in the area between the nostrils (nasal ulcers), nasal surgery, or nasal trauma and not completely healed yet (Corticosteroids may delay wound healing.)
- It is not recommended to be used in this age group because of the limited use experience between 2-6 years.
- Nasal corticosteroids, including N-CORT, have been shown to suppress growth in children and adolescents. Your doctor will closely monitor the results regarding the suppression of growth and will regularly measure the height of your children and determine the possible effects of the treatment on the growth rate.
- If you have impaired vision or have had eye problems such as increased intraocular pressure, eye pressure (glaucoma) or cataracts (Corticosteroids have been reported to cause such eye problems. Your doctor will perform regular eye examinations and follow you closely.)
- If high doses of nasal steroids are taken for a long time, systemic effects can be seen. These include disorders associated with weight gain and increased blood pressure due to increased blood cortisone levels (Cushing's syndrome, Cushingoid features), adrenal gland suppression, growth retardation in children and adolescents, opacification of the lens of the eye (cataract), and increased intraocular pressure (glaucoma) and more rarely psychological or behavioral effects such as psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (especially in children).

- **Operations or stressful periods**

Your doctor may recommend that you take this medicine at a higher dose than usual for medical reasons. Tell your doctor if your dose has been increased and you are going to have an operation or if you are not feeling well. Because, higher doses of this drug than normal can weaken your body's ability to overcome the stress or to heal. If this happens, your doctor may decide that you need additional treatment with another medication to help.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

N-CORT with food and drink:

N-CORT is used as a nasal spray. It does not have any interactions with food and drinks due to its method of administration.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

If you are pregnant, you should not use N-CORT Nasal Spray. Therefore, pregnancy status should be evaluated before initiation of the treatment.

Your doctor may recommend you to use the medicine if he/she thinks that benefit to the mother justifies the potential risk to the fetus.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

If you have to take N-CORT Nasal Spray during breast feeding, you should discontinue breast feeding in order to preserve the baby from small amounts of drug which excretes into human milk.

Driving and using machines

N-CORT has no known effect on the ability to drive or use machines.

Important information about some of the excipients of N-CORT

N-CORT contains benzalkonium chloride as an excipient. This substance is an irritant, which may cause skin reactions.

Other medicines and N-CORT

There is no evidence showing interaction of N-CORT with any medicinal product.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use N-CORT?

- **Instructions for use and dosage/frequency of administration:**

Your doctor will tell you how and at which doses you need to take your drug.

Adults and patients above 12 years of age;

The recommended starting dose is 220 mcg per day as two sprays in each nostril once daily. When symptoms have been controlled, the dose is reduced to 110 mcg as one spray in each nostril once a day.

An improvement of symptoms may be seen at the first day after initiation of treatment in some patients. However, for maximum benefit several days of treatment may be necessary.

Children between 6 and 12 years of age:

The recommended dose is 110 mcg per day as 1 spray in each nostril once daily. In patients with more severe symptoms the dose of 220 mcg once daily may be used. Once symptoms have been controlled, treatment may be maintained at minimum effective dose.

It is not recommended to be used in this age group because of the limited use experience between 2-6 years.

It is not recommended to use for more than 3 months in children under 12 years of age until further evidence is obtained.

An adult should help children while using this drug.

For children under 2 years:

Safety and efficacy in children under 2 years has not been established. Therefore, it is not recommended for children under 2 years of age.

• **Route of administration and method:**

N-CORT is used by intranasal route only and should be used regularly for optimal efficacy.

• **Administration of N-CORT:**

N-CORT is only used by spraying into the nose.
Before using N-CORT, clean your nostrils.

1. Preparing the bottle

- Remove the cover by pushing it upwards.
- Shake the bottle gently before use.



2. Before using Nasal Spray for the first time

- Hold the bottle upright.
- Direct the spray away from yourself.
- Fill the pump by pressing the nozzle downwards.
- Press and release 5 times.
- Spray until you get a fine spray.
- Spray is now ready to use.



Correct position Wrong position



Correct position

Wrong position

3. Use of spray

- Close one of your nostrils by pressing with your finger.
- Hold the bottle upright and insert the nozzle into your nostril to the level that will not disturb you.
- While your mouth is closed and breathing smoothly through your nose, apply a spray by pressing the nozzle of the bottle.

4. Then exhale through your mouth.

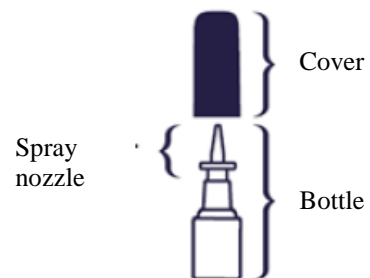
5. Follow the procedures described in item 3 and 4 above for the other nostril.

6. After using the spray

- Carefully wipe the nozzle with a soft cloth or tissue after each use and
- Place the cap on top of the spray nozzle.

If you have not used the nasal spray for more than 2 weeks:

- To fill spray nozzle with spray you should prepare it for use.
- During this application, keep the spraying point of the nozzle away from you.
- Spray once into the air before you start using it.
- Shake the bottle gently before each use.



Cleaning the spray

If the spray does not work, the nozzle may be clogged. **Never** try to open the clogging. Do not attempt to extend the small spray hole with a needle or a hard object, as the spray mechanism could be damaged.



Nasal spray should be cleaned at least once a week. It can be cleaned more often if clogged.

Instructions for cleaning the spray:

1. Remove the cover.
2. Only gently pull the spray nozzle.



3. Soak the cap and spray nozzle in hot water for a few minutes.
4. Then rinse in cold running tap water.



5. Remove excess water by shaking or tapping gently.
6. Allow to dry.
7. Reattach the spray nozzle
8. Spray the unit until a fine spray is reached.
9. Use as usual.

Starting from the first application, the bottle should be discarded after 120 sprays or in 2 months (16.5 g/bottle).

Any remaining suspension should not be transferred to another bottle.

Follow these instructions unless recommended otherwise by your doctor.

Your doctor will tell you how long you will use N-CORT. Do not stop treatment earlier than you should, otherwise your symptoms may be seen again.

• **Different age groups:**

Use in Children:

Children between 6 and 12 years of age: The recommended dose is 110 mcg per day as 1 spray in each nostril once daily. In patients with more severe symptoms the dose of 220 mcg once daily may be used.

Once symptoms have been controlled, treatment may be maintained at minimum effective dose

It is not recommended to be used in this age group because of the limited use experience between 2-6 years.

For children under 2 years:

Safety and efficacy in children under 2 years has not been established. Therefore, it is not recommended for children under 2 years of age.

Use in elderly:

Efficacy and safety of N-CORT in elderly patients have not been established.

• **Special cases of use**

Kidney/liver failure:

Safety and efficacy of N-CORT in the patients with renal and hepatic failure have not been studied.

If you have impression that the effect of N-CORT is very strong or weak, tell a doctor or pharmacist.

If you use more N-CORT than you should:

It is important that you take the dose recommended by your doctor or as indicated by your pharmacist. You should only use it as recommended by your doctor; if you use more or less, your symptoms may worsen.

An overdose is not expected to cause problems. However, if you take the entire contents of the bottle by mouth, you may experience stomach or bowel discomfort.

If you use more N-CORT than you should, tell your doctor or pharmacist.

If you forget to use N-CORT:

If you miss a dose and the time of the next dose is not close, take the dose as soon as you remember.

Do not take a double dose to make up for a forgotten dose.

If you stop using N-CORT

If you stop N-CORT without consulting to your doctor, your allergy symptoms may reoccur.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the followings stop using N-CORT and immediately inform your doctor or go to the nearest emergency department:

- Hypersensitivity reaction (rash, hives, itching, difficulty breathing and swallowing, swelling of lips, face, throat and tongue)
- Generalized swelling of the skin on eyelids, around the mouth and hands and feet with

itching

All of these are very serious side effects. If you have any one of these side effects, then it indicates that you have serious allergy to N-CORT. You may require medical intervention or you should be hospitalized.

All these very severe side effects are observed very rarely.

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

Other side effects:

Common

- Runny nose, headache, sore throat and / or cough
- Nose bleeding
- Inflammation / irritation of the airways (bronchitis)
- Heartburn or indigestion (dyspepsia)
- Flu-like symptoms (fever, muscle pain, weakness and / or fatigue)
- Dental disorders

Rare

- Perforation of the middle part of the nose (nasal septum)

Not known

- Irritation and dryness in the nose
- Fluid collection and obstruction in the air cavities (sinuses) on the face
- Nasal congestion
- Sneezing
- Taste and odor changes
- Nausea
- Insomnia, dizziness or fatigue
- Shortness of breath (dyspnea)
- Decreased blood cortisol levels
- Ocular lens opacification (cataract), increased intraocular pressure (glaucoma)

Additional side effects in children

If your child is taking this medication, your child's growth rate may be affected; your doctor will want to measure your child's height regularly and your doctor may reduce the dose. In addition, your doctor may consider referring your child to a pediatrician.

As with other corticosteroids administered nasally, nasal septum perforations (perforation in middle section in the nose) and nasal congestion (nasal congestion) have been reported rarely.

Nasal corticosteroids may cause systemic effects, especially when used at high doses for a

long time. Growth retardation has been reported in children using nasal steroids.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store N-CORT

Keep this medicine out of the sight and reach of children.

Store at room temperature below 25 °C in a dry place and in its original packaging.

Discard opened N-CORT after 2 months.

Use in accordance with expiry date.

Do not use this medicine after the expiry date which is stated on the packaging.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

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